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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,265	11/25/2003	Vincent Fischetti		4611

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EXAMINER	
KIM, TAEYOON	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,265	FISCHETTI ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Terminal Disclaimer filed on Dec. 26, 2006 has been received and entered into the case.

Claims 82-102 are pending and have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 94-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 94 and 95 recite "further" process steps of administering a certain amount of enzyme units. These additional process steps do not make sense, given the fact that previous claim 82 is a product claim and cannot contain any actual positive process steps. Similarly, claims 96-98 recite the process steps of administering the enzyme-containing therapeutic agent of claim 82 intravenously (claim 96), intramuscularly (claim 97) or subcutaneously (claim 98). This additional process step does not make sense, given the fact that previous claim 82 is a product claim and cannot contain any actual positive process steps.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 82-85 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by Gasson (EP 0510907 A2).

Claims 82-85 and 102 are drawn to a composition comprising (1) a phage encoded lytic enzyme specific for a bacteria and (2) a carrier suitable for parenteral delivery of the enzyme (claim 82); a limitation to the lytic enzyme being for the treatment of *Pseudomonas* (claim 83); a limitation to the lytic enzyme being for the treatment of *Streptococcus* (claim 84); a limitation to the lytic enzyme being for the treatment of *Staphylococcus* (claim 85); a limitation to the enzyme being lytic enzyme not being shuffled, chimeric and holin lytic enzyme (claim 102).

Gasson teaches a composition comprising a lytic enzyme specific for *Clostridium tyrobutricum* (see page 2, lines 16-18), and also teaches that *Pseudomonas, Streptococcus, Staphylococcus* can be destroyed by the lysin (lytic enzyme) (see p.2, lines 26-30), said composition being suitably added to "water" (see page 2, line 58), which is a suitable parenteral carrier. The enzyme may also be combined with topical carriers in the form of a lotion cream or ointment (page 3, lines 4-6) which also may be administered parenterally, for example subcutaneously. It is noted that the described compositions are not *per se* intended for parenteral administration, as recited in applicant's claims. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim

drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See* In re Casey, 152 USPQ 235 (CCPA 1967) and In re *Otto,* 136 USPQ 458, 459 (CCPA 1963). In the instant case, Gasson's water-containing enzyme composition as well as the topical compositions can be administered parenterally. A holding of anticipation is therefore required.

The lytic enzyme of Gasson is not specified as shuffled, chimeric and holin lytic enzyme, and since it is directly isolated from bacteriophage, the lytic enzyme of Gasson is considered as a lytic enzyme but not shuffled, chimeric and holin lytic enzyme.

Thus, the reference anticipates the claimed subject matter.

Claims 82, 84, 86-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischetti et al. (US 5,604,109).

Claims 82, 84, 86-93 are drawn to a composition comprising (1) a phage encoded lytic enzyme specific for a bacteria and (2) a carrier suitable for parenteral delivery of the enzyme (claim 82); a limitation to the composition for the treatment Streptococcus (claim 84); a limitation to the composition further comprising a buffer that maintains pH between about 4-9 (claim 86); a limitation to the composition further comprising a buffer that maintains pH between about 5.5-7.5 (claim 87); a limitation to the composition further comprising a reducing agent (claim 88); a limitation to the reducing agent being dithiothreitol (claim 89); a limitation to the buffer comprising a metal chelating reagent (claim 90); a limitation to the metal chelating reagent being ethylenediaminetetracetic disodium salt (claim 91); a limitation to the buffer being a

citrate-phosphate buffer (claim 92); a limitation to the composition further comprising a bactericidal or bacteriostatic agent (claim 93).

Fischetti et al. teach a composition comprising a Group C *Streptococcal* lytic enzyme specific for Group A *Streptococci* (see Example 1) dissolved in water (column 4, line 49), which is a suitable parenteral carrier. It is noted that the described compositions are not *per se* intended for parenteral administration, as recited in applicant's claims. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *See* In re Casey, 152 USPQ 235 (CCPA 1967) and In re *Otto,* 136 USPQ 458, 459 (CCPA 1963). In the instant case, a water-containing enzyme composition of Fischetti et al. can be administered parenterally.

Fischetti et al. also teach the limitations of pH, dithiothreitol, EDTA disodium salt, citrate-phosphate buffer and bactericidal or bacteriostatic agent (see claims 9-18, and Examples).

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 82-85 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gasson (supra).

Claims 82-85 and 99 are drawn to drawn to a composition comprising (1) a phage encoded lytic enzyme specific for a bacteria and (2) a carrier suitable for parenteral delivery of the enzyme (claim 82); a limitation to the lytic enzyme being for the treatment of *Pseudomonas* (claim 83); a limitation to the lytic enzyme being for the treatment of *Streptococcus* (claim 84); a limitation to the lytic enzyme being for the treatment of *Staphylococcus* (claim 85); a limitation to the composition further comprising a complementary agent potentiating the bactericidal activity of the enzyme (claim 99).

Gasson anticipates the limitations of claims 82-85 and therefore renders the current invention obvious (see above).

It would have been obvious for an ordinary skilled person in the art to select a species of bacteria and the corresponding lytic enzyme specific for the treatment of such bacteria (*Pseudomonas, Streptococcus* or *Staphylococcus*). A person of ordinary skill in the art would have been motivated to pick a specific species of bacteria and a specific lytic enzyme for the bacteria because these bacteria cause serious illness and therefore the treatment of such infection would be necessary. Furthermore, Gasson teaches a list of bacteria which can be destroyed by specific lytic enzymes.

Although Gasson does not particularly disclose the group of different species of antibiotics as listed in claim 99, it would have been obvious for an ordinary skilled person in the art at the time of the invention made to combine the lytic enzyme of Gasson with antibiotics listed in the claim.

The skilled artisan would have been motivated to make such a modification because the lytic enzyme of Gasson and antibiotics listed in the claim 99 would have the same purpose, which is to kill bacteria. M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re* Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture

comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte* Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 82 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischetti et al (supra).

Claims 82 and 99 are drawn to a composition comprising (1) a phage encoded lytic enzyme specific for a bacteria and (2) a carrier suitable for parenteral delivery of the enzyme (claim 82); a limitation to the composition further comprising a complementary agent potentiating the bactericidal activity of the enzyme (claim 99).

Fischetti et al. anticipates each and every limitation of claim 82 and therefore renders obviouis (see above).

Although Fischetti et al. do not particularly disclose the group of different species of antibiotics as listed in claim 99, it would have been obvious for an ordinary skilled person in the art at the time of the invention made to combine the lytic enzyme of Fischetti et al. with antibiotics listed in the claim.

The skilled artisan would have been motivated to make such a modification because the lytic enzyme of Fischetti et al. and antibiotics listed in the claim 99 would have the same purpose, which is to kill bacteria. M.P.E.P. §2144.06 states "It is prima

facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re* Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte* Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 82 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 31, 47, 51, 115 and 121 of copending Application No. 10/855,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications contain claims drawn to a composition having a lytic enzyme produced by bacteriophage and a carrier suitable for parenteral delivery.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 82, 84, 99, 100 and 102 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58, 60, 61, 64-66, 68, 70, 72 and 76 of copending Application No. 11/027,959. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications contain claims drawn to a composition having a lytic enzyme produced by bacteriophage and a carrier suitable for parenteral delivery. Specifically, the claims of '959 anticipate the limitation of the claims of the current invention because '959 application claims a specific lytic enzyme for *Streptococcus peumoniae*, and therefore renders the current claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 82 and 84 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 11/186,018. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications contain claims drawn to a composition having a lytic enzyme produced by bacteriophage and a carrier suitable for parenteral delivery. Specifically, the claims of '018 anticipate the limitation of the claim 84 because '018 application claims a specific lytic enzyme for *Streptococcus*, and therefore renders the current claim obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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